Attorney Docket No.: B0410/7275D1

Filed: June 27, 2003

Inventors: Gambale et al. **Amendment and Reply** Page 2

U.S. App. No. 10/609,053

Amendments to the Specification:

Please replace the paragraph running from page 2, line 12, through page 3, line 3, with the following paragraph:

The present invention provides various mechanisms for positioning the distal end of a catheter at its intended treatment site within a patient. Two approaches to positioning the distal end of the catheter are disclosed. In a first embodiment, the distal end of the catheter employs a collapsible superstructure which causes the distal tip of the catheter mounted thereto to change direction so that the distal opening of the catheter can be directed to the intended tissue site. The superstructure is comprised of two flexible vanes veins mounted along the side wall of the distal end of the catheter parallel to the longitudinal axis of the catheter that are biased to bow radially outward upon an application of a compressive force delivered through a pull wire that extends through the catheter. The expansion of the flexible vanes veins increases the profile of the catheter at its distal end such that the vanes veins will contact interior wall surfaces of the body lumen or organ in which the catheter is placed thereby preventing unwanted lateral movement of the catheter. The distal tip of the catheter is mounted to the distal end of one of the vanes so that the vane lies along the longitudinal axis of the catheter when the vanes are unstressed. Therefore, when the vanes are bowed radially outward the angular displacement of the vane at the connection point with the distal tip of the catheter, away from the longitudinal axis of the catheter, causes the distal tip to have a corresponding angular displacement. The variable angular displacement of the tip during displacement of the vanes provides a steering mechanism for the tip of the catheter so that it may be navigated to a particular tissue location.

Please replace the Abstract with the following Abstract:

The present invention provides a catheter positioning system which serves to control and stabilize a distal end of a catheter at a treatment site within a patient so that a Attorney Docket No.: B0410/7275D1

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medical procedure can be performed with accuracy. Generally, the positioning system operates by providing a deformable mechanical members at the distal end of the catheter which can be operated from the proximal end of the catheter to extend radially outward to engage surrounding tissue adjacent to treatment site. In one embodiment of the invention a flexible superstructure comprising the plurality of flexible vanes veins extending longitudinally along the distal end of the catheter can be deformed to bow radially outward to engage surrounding tissue. The distal tip of the catheter joined to one of the vanes veins was correspondingly displaced or rotated angularly as the vanes veins bow outward. In another embodiment radially projecting fingers are joined to the distal end of the catheter, which remain retracted during navigation of the catheter to the treatment site then are extended outward to penetrate the tissue and secure the catheter at the treatment site upon being actuated from the proximal end of the catheter by a physician. Methods of positioning a catheter are also disclosed. The inventive device and method are particularly useful in catheter based procedures carried out in large body lumens or in cavities of body organs. In particular, the invention may be useful in delivering implants percutaneously through the left ventricle into the myocardium of the heart.